510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k111204

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
Assayed hematology parameters: WBC, RBC, HGB, MCV, PLT

D. Type of Test:
Quantitative

E. Applicant:
Streck Inc.

F. Proprietary and Established Names:
CELL-DYN 22 Plus Calibrator

G. Regulatory Information:

1. Regulation section:
   21 CFR § 864.8150 Calibrator for cell indices
2. Classification:
   Class II
3. Product code:
   KRX – Calibrator for cell indices
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   CELL-DYN 22 Plus Calibrator is manufactured for calibration of the CELL-DYN Emerald 22 system.

   Assayed parameters include: WBC (10^9/L), RBC (10^{12}/L), HGB (g/dL), MCV (fL), PLT (10^9/L).
2. Indication(s) for use:
   Same as intended use
3. Special conditions for use statement(s):
   For prescription use only
4. Special instrument requirements:
   CELL-DYN Emerald 22

I. Device Description:
CELL-DYN 22 Plus Calibrator is a product that may contain any or all of the following: stabilized human red blood cells, human, mammalian or simulated white blood cells and a platelet component in a preservative medium. The product is packaged in polypropylene plastic vials containing 2.5 mL. The closures are polypropylene screw caps with polypropylene liners. The vials will be packaged in a four welled vacuum formed clam-shell container with the product information sheet/assay sheet. The product must be stored at 2-10°C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Cal-Chex

2. Predicate K number(s):
   k840261
3. Comparison with predicate:

Similarities		
Item	Device: CELL-DYN 22 Plus	Predicate: Cal-Chex
Intended Use	CELL-DYN 22 Plus Calibrator is manufactured for calibration of the CELL-DYN Emerald 22 system. Assayed parameters include: WBC (10^9/L), RBC (10^{12}/L), HGB (g/dL), MCV (fL), PLT (10^9/L).	Cal-Chex is used to calibrate multi-parameter hematology analyzers. Same assayed parameters including HCT, MCH and MCHC.
Open Vial Stability	5 days	Same
Closed Vial Stability	45 days	Same
Reagents	The product may contain any or all of the following: stabilized human or mammalian red blood cells, human, mammalian or simulated white blood cells and a platelet component in a preservative medium	Same
Storage Conditions	2-10°C	Same

There is no difference between the predicate and the new device.

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Proposed Standard-Second Edition

L. Test Principle:

The CELL-DYN 22 Plus Calibrator was designed to calibrate the Abbott CELL-DYN Emerald 22 instrument. The assayed values are traceable to reference methods. The product is for *in-vitro* diagnostic use to calibrate WBC, RBC, HGB, MCV, and PLT.

M. Performance Characteristics:

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Precision performance: Data was collected internally and at two external sites across seven different CELL-DYN Emerald 22 instruments with multiple operators using 3 lots of CELL-DYN 22 Plus Calibrator. The external sites performed 10 consecutive runs across two different instruments with separate vials of calibrator from each lot. Internally, Streck performed 10 consecutive runs per lot across three instruments. The acceptance criteria are based on a compilation of the %CV for each measurand. All %CV values were within

the acceptable threshold value as shown below,

	Measurand %CV				
Lot	WBC	RBC	HGB	MCV	PLT
09210	2.29	2.04	1.80	0.81	5.58
09202	2.51	2.15	1.50	0.90	5.17
09189-1	2.99	1.68	1.74	0.93	5.30
Maximum CV% Acceptance Criteria	10	10	10	10	10

Run-to-run precision was evaluated in a 10-run repeatability study performed with each calibrator lot and with a fresh whole blood sample collected in K_2EDTA. Parameter specific SDs and CVs reported with whole blood were compared to those reported with three individual lots of the calibrator. Repeatability attributes of the CELL-DYN 22Plus Calibrator parallel those reported with fresh whole blood with %CV values within acceptable limits..

b. *Linearity/assay reportable range:*
Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Value assignment: A minimum of three vials were tested on the CELL-DYN Emerald 22 instruments. Duplicate testing on each vial was performed consecutively for a minimum of three test events performed on different dates. The data were entered into the validated QC link database program to calculate the mean, standard deviation, and coefficient of variation for each parameter analyzed. Final assay assignment values were determined using data collected and established product performance characteristics. Expected range values assigned to the assay were based on the standard deviation of the assay data. Assay values were assigned to the calibrator based on ±2.5 SD for each measurand.
Open vial stability: A 5-day open-vial stability claim was verified using three lots of the CELL-DYN 22 Plus Calibrator. Each lot was tested on days 1, 5 and at minimum one intermediate time interval.

Closed vial stability: A 45-day closed-vial stability claim was verified using three lots of the CELL-DYN 22 Plus Calibrator. Each lot was tested at a minimum every 14 days over a minimum period of 45 days.

The acceptance criteria for open and closed vial stability is based on a compilation of the %CV for each measurand over the data collected across 7 different CELL-DYN Emerald 22 instruments, at 3 sites, throughout the product dating claim. Reported %CV for each measurand was within the threshold value (< 10% CV).

d. *Detection limit:*
Not applicable

e. Analytical specificity:
Not applicable

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Not applicable

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
The end-user is instructed to refer to the product assay sheet accompanying the product information sheet.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.